

Remarks

Claims 1-75 are pending in the application, and are subject to a second restriction requirement.

Response to Restriction Requirement

Applicants elect, with traverse, Group I (claims 1, 3 in part, 4, 6 in part, 7, 9 in part, 68 in part, and 69 in part), drawn to synthetic peptides comprising the motifs of XBBBXXBX and XBXXBBBX, for the reasons outlined below.

First, Applicants respectfully point out that in reciting the sequences, the Examiner added a letter to one of the sequences. Please note that instead of reciting the formula "XBXXBBBX", the Examiner mistakenly recited the sequence "XBXXXBBBX", which has an additional X. Applicants will use the correct formula in this response.

The Examiner alleges at page 4 of the Office Action that the inventions are distinct from one another because Groups I, II, and XI are structurally different products comprising different amino acid sequences. The Examiner also alleges that SEQ ID NO:10 does not have any of the motifs required for Groups I and II. The Examiner then asserts that a search for the peptides of Group I would not be coextensive with the search for the peptides of Group II or Group XI, due to the different sequences included in each group. The Examiner further alleges that the examination of all structures would require different searches of the U.S. Patent and scientific literature, and would require the consideration of different patentability issues. In addition, the Examiner asserts that searches required for the peptide groups would not be co-extensive.

The Examiner alleges at page 5 of the Office Action that Groups III to X differ in the method objectives, methods steps and parameters, and in the reagents used.

The Examiner also alleges at page 5 that Invention I is related to inventions III, V, VII and IX as product and processes of use. The Examiner asserts that the product of Group I can be used in all the process of Groups III, V, VII and IX, in addition to being used in a process of raising an antibody.

The Examiner further alleges that Invention II is related to inventions IV, VI, VIII and X as product and processes of use. The Examiner alleges that Group II can be used in all the processes of Groups III, V, VII, and IX, in addition to being used in a process of raising an antibody. Applicants respectfully point out that the inventions which the Examiner alleges are related to invention II, namely inventions IV, VI, VIII and X, are not the same groups recited by Examiner regarding processes related to Group II. The Examiner instead recited Groups III, V, VII, and IX. Applicants assume that the Examiner intended to allege that Group II can be used in all the processes of Groups IV, VI, VIII, and X, and will respond accordingly.

Applicants respectfully disagree with the allegations of the Examiner.

Restriction is proper only if the pending claims represent independent or distinct inventions, *and* there is a serious burden in searching and examining the entire application. MPEP §803. Here, Examiner cannot show that claim Groups I, II, III, IV, V, VI, VII, VIII, IX, X, and XI represent independent or distinct inventions and that there is a serious burden on searching and examining these claim groups in one application. In addition, there is no serious burden in searching the claimed consensus peptides of the invention, regardless of whether the four peptide consensus sequence motifs are independent or distinct, or whether SEQ ID NO:10 conforms specifically to one of the consensus sequences. Thus, to the extent discussed below, the restriction requirement is improper and should be withdrawn.

Restriction of Groups I, II, and XI is Not Proper

According to MPEP 802,

“The term “distinct” means that two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process and product made, etc., but are capable of separate manufacture, use, or sale as claimed, . . . “

Contrary to the Examiner’s assertion, the subject matter of the claims is not capable of separate manufacture, use or sale. All 75 claims require the presence of a peptide classified in class 530, subclass 300. In addition, all of the claims of Groups I-X require the presence or use of the peptide consensus sequence motifs of Group I or Group II, or depend from such a claim. In addition, both claims of claim Group XI require the presence of SEQ ID NO:10.

Applicants again respectfully submit that the consensus sequences are not distinct. Regarding the consensus sequence motifs of Groups I and II, all four peptides or consensus sequence motifs are synthetic peptides of six or eight residues with a high affinity for glycosaminoglycan and proteoglycans, and B is arginine or lysine or a combination of arginine and lysine for each of the four peptides/consensus sequences. The application as filed shows that peptides comprised of tandem repeats of the sequences XBBBXXBX, XBXXBBBX, XBBXXBX, and XBXBBX, having similar molecular weights, bind heparin and proteoglycans with similar affinities, and exhibit similar heparin neutralization activities *in vivo* (see Tables I, II, and III).

Moreover, the application provides that the directionality of the sequences does not matter, i.e., they are just as active when tested in their reverse orientations. For example, the heparin binding affinity of (ARKKAACA)₃, representative of consensus sequence XBBBXXBX, is about 135 nM, while that of the reverse sequence (AKAACKRA)₃, representative of consensus sequence XBXXBBBX, is about 132 nM (Table II). In addition, the six-mer tandem repeat (AKKARA)₄, representative of consensus sequence XBBXXBX, has a similar molecular weight (M_r 2520) and dissociation constant (174 nM) to the tandem repeat eight-mers mentioned above (Table II).

Applicants also believe that in performing a patentability search in the context of the consensus sequences of the invention, the Examiner will necessarily uncover art pertaining to any such sequence. Thus, no undue burden is placed upon the Examiner to search for all four peptides/consensus sequences at the same time.

The peptides of the consensus sequence formulas recited in the claims of Groups I and II are all classified in class 530, subclass 300. Furthermore, the sequence recited in Group XI (SEQ ID NO:10), although not conforming specifically to the formulas recited for Groups I and II, is also classified in class 530, subclass 300. Applicants respectfully point out that SEQ ID NO:10, "TyrProThrGlnArgAlaArgTyrGlnTrpValArgCysAsnPro," which the Examiner alleges does not satisfy the motif requirements of Groups I and II, is only recited in the claims of Group XI (claims 65 and 67) and does not depend from the specific sequence motifs of Groups I and II. Claim 65 is an independent claim reciting SEQ ID NO:10 and claim 67 depends from claim 65. Thus, restriction is not proper as Groups I, II, and XI are not distinct.

In addition, there is no serious burden in searching the claimed invention, regardless of whether the claims groups are independent or distinct. Applicants note that all of the peptides and motifs of the claimed invention have been classified by the Examiner in class 530, subclass 300. Here, the most efficient way to search the present claims of Groups I, II, and XI, would be to concentrate on the peptide motifs classified in class 530, subclass 300, because all claimed peptides are in this classification.

Because a search of the peptides of Group I would encompass the peptides of Groups II and XI, Applicants believe there is no serious burden in searching and examining Groups I, II, and XI in the same application. It is unlikely that a search of one claim group would reveal no art that is pertinent to the others. Applicants therefore respectfully request reconsideration and withdrawal of the restriction requirement with respect to Groups I, II, and XI.

Claim Groups III to X Are Not Distinct

Applicants submit that Groups III, IV, V, VI, VII, VIII, IX, and X should not be restricted into eight groups and request that the eight groups be combined into one group with the other groups. The discussion above with respect to searching the peptides classified in class 530, subclass 300 (Groups I, II, and XI) applies equally here, because all of the claims of Groups III to X relate to basic methods of using the peptides of Groups I and II.

Inventions are distinct only if they are 1) classified separately, 2) have acquired separate status in the art when classified together, or 3) require a different field of search (i.e., it is necessary to search for one invention in places where no pertinent art exists for the others). In order to establish reasons for insisting upon restriction, the Examiner must show by appropriate explanation that the inventions are distinct. MPEP § 808.02.

With regard to Groups III and IV, the groups are not classified separately under § 808.02(A), as Examiner has classified each group in the identical class (530) and subclass (413). With regard to Groups V-X, the groups are not “classified separately” under § 808.02(A), as all are classified in class 514, subclass 2. Groups V and VI are additionally classified in subclass 34.

Groups III, IV, V, VI, VII, VIII, IX, and X do not represent separate inventive effort under § 808.02(B), as they all relate to basic methods for using the claimed peptides, based on the biological activity and function of the peptides. For example, the Examiner notes at

pages 2-4 that the claims of Groups III to X relate to methods of using the peptide motifs classified in class 530, subclass 300. As described above, all claimed peptide motifs are classified in class 530, subclass 300. It is USPTO practice to direct a patentability search to a compound itself, even if the claims are directed to a method of using the compound.

Furthermore, Groups III and IV do not require a different field of search under § 808.02(C), because they have the identical classification and subclassification (class 530, subclass 413). Applicants note that in performing a patentability search for use of the peptides of the invention, the Examiner will necessarily uncover the prior art pertaining to the claims of Groups III and IV, because all relate to methods of use of peptides classified in class 530, subclass 300. In addition, the claims of Groups III and IV are classified in the same class as the claimed peptides. Therefore, no undue burden is placed on the Examiner to search for methods of use of the peptides in Groups III and IV and it is unlikely that a search of one claim group would reveal no art that is pertinent to the other.

In addition, Groups V, VI, VII, VIII, IX, and X do not require a different field of search under § 808.02(C), because they have the identical classification and subclassification (class 514, subclass 2), although Groups V and VI are additionally classified under subclass 34. As noted above, the Examiner admits at pages 3-4 that all of the claims of Groups III to X relate to methods of using peptides classified in class 530, subclass 300, e.g., the peptides of Groups I and II. Thus, in performing a patentability search for use of the peptides of the invention, the Examiner will necessarily uncover the prior art pertaining to the claims of Groups V to X, because all relate to methods of use of peptides classified in class 530, subclass 300. Therefore, no undue burden is placed on the Examiner to search for methods of use of the peptides in Groups V to X and it is unlikely that a search of one claim group would reveal no art that is pertinent to the other.

Therefore, Groups III, IV, V, VI, VII, VIII, IX, and X fail to satisfy the criteria set forth in MPEP § 808.02, and are not distinct.

The Examiner has provided no reasoning to support the allegation that Groups III, IV, V, VI, VII, VIII, IX, and X represent distinct inventions, but has merely stated a conclusion that the inventions are distinct. Such a conclusory statement is inadequate to establish that the claim groups represent distinct inventions. MPEP §§ 808.02(B) and 816. The present restriction requirement is therefore improper, and should be withdrawn.

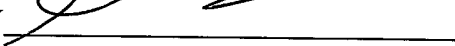
Conclusion

Applicants respectfully submit that Groups I, II, III, IV, V, VI, VII, VIII, IX, X, and XI are not distinct. Furthermore, because a single search of the peptide groups of claim Group I, which is identically classified with claim Groups II and XI, would necessarily uncover prior art relevant to claims Groups II, III, IV, V, VI, VII, VIII, IX, X, and XI, no undue search burden is placed on the Examiner. For these reasons, Applicants respectfully request withdrawal of the restriction requirement with respect to Groups I, II, III, IV, V, VI, VII, VIII, IX, X, and XI.

Applicants believe this response to be fully responsive to the outstanding Restriction Requirement and request prosecution on the merits.

Respectfully submitted,

JAMES D. SAN ANTONIO et al.

BY 
DANIEL A. MONACO
Registration No. 30,480
DRINKER, BIDDLE & REATH, LLP.
One Logan Square
18th and Cherry Streets
Philadelphia, PA 19103-6996
(215) 988-3312
(215) 988-2757 – Fax
Attorney for the Applicant